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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,565	11/13/2003	Harvey A. Fishman	S02-296/US	8264

30869 7590 03/29/2005

LUMEN INTELLECTUAL PROPERTY SERVICES, INC.
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EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,565

Applicant(s)

FISHMAN ET AL.

Examiner

Allison M Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 24, 26-32, 34-35 and 38 is/are rejected.
- 7) ☒ Claim(s) 24, 25, 33 and 36-38 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/13/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Priority

Acknowledgement is made of applicant's claim for priority as a CIP of US application 10/184,210 filed 06/27/2002, which further claims priority to provisional application 60/301,934 filed 06/29/2001.

Status of Application

Claims 24-38 are pending in the current application. Claims 1-23 were cancelled by applicant on 8/16/2004.

Claim Objections

Claims 24 and 38 are objected to because of a minor spacing problem: there should be four listed components of the neuronal devices of claims 24 and five listed components of the neuronal device of claim 38, as follows:

- (a) a housing having a surface biocompatible with at least a portion of a neuronal cell;
- (b) an aperture in said surface;
- (c) a reservoir connected to said aperture; and
- (d) a flow regulator in operable relationship with fluid in said reservoir for moving said fluid to said aperture.

Claim 38 should have the additional fifth component:

- (e) at least one of a flexible housing, a flexible membrane pump, or a light sensitive polymer flow regulator.

Appropriate correction is required.

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Claims 25, 33 and 36-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-31, 34 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim 27 and its dependent claims 28-31 are indefinite because it is unclear if the biocompatible surface of (b) is part of the housing of (a), or if the biocompatible surface (b) is separate from the housing of (a).

Applicant's claim 29 is further indefinite because it does not sufficiently define the size of the device, as it only recites: "said device is of a size to fit into a subretinal or epiretinal space." The size of the subretinal or epiretinal space can vary greatly depending on the species, as the claim is not limited to any one species; additionally, even within a single species the size of the device can vary greatly, as it can be an unobtrusive microelectrode ranging in size from microns to millimeters, or it can fill the entire sub- or epiretinal space, spanning several square centimeters.

Applicant's claim 31 is further indefinite, as it appears to fail to further limit the parent claim 27. Claim 27 comprises a reservoir connected to the aperture; claim 31 requires the device of claim 27 to comprise a well connected to the aperture. It appears the well and the reservoir are the same, if not, it is unclear how they differ, and the structure relationship between the well and reservoir, as well as the purpose and/or effect of the well is unclear.

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Applicant's claim 34 is indefinite because the structural relationship between the two layers and the housing (claim 32 (a)) is unclear. It is not clear if the first layer (claim 34 (a)) is situated within the housing, and the second layer comprises the housing, or if both layers comprise the housing, or if the layers are juxtaposed on top of one another, and there is no housing.

Applicant's claim 38 is indefinite because the purpose, effect, design and structural relationship of the flexible membrane pump and light sensitive polymer flow regulator within the device of claim 38 are not clear. There is no description of a membrane pump or a polymer flow in the device of claim 38; therefore it is not clear how these components function within the device. Applicant has not provided any information regarding the effect or intent of inclusion of the flexible membrane pump and light sensitive polymer flow regulator. Because one cannot determine what the flexible membrane pump and light sensitive polymer flow regulator accomplish in the device of claim 38 and applicant has provided no information to this effect, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 24 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Fishman et al (ARVO Annual Meeting Abstract Search and Program Planner, Abstract No. 2846, May 05-10, 2002).

Fishman et al teach a neuronal device comprised of a biocompatible silicon nitride surface stamped with a microcircuit-like pattern of biomolecules (which applicant calls a micropattern), the surface also comprises a microaperture that is connected by a microfluidic device (which applicant calls a flow regulator) to a reservoir of neurotransmitters. The

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microcircuit-like pattern is effective to direct growth of neuronal processes to the apertures, which serve as stimulation sites. Therefore the reference anticipates the claimed subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 26-32, and 34-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 36, 40 and 43 of copending Application No. 10/184,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because current claims 24, 27, 31, 32 and 34-35 disclose neuronal devices for modulating neuronal activity comprising a device with a surface that is modified to receive a neuronal cell process, an aperture, a reservoir connected to the aperture, and a flow regulator in operable relationship with fluid in said reservoir for moving said fluid to said aperture. Claims 26 require the device to be micropatterned. Claim 28 requires the micropattern to comprise bioactive agents to direct the growth of the neuronal cell processes. Claim 29 requires the device to function as an ocular implant to be implanted in the subretinal or epiretinal space. Claim 30 requires the device to comprise at least one photodiode.

Claim 1 of the copending application is directed to a substrate with a surface configured to receive a cell process and wherein the surface has a micropattern effective to direct the growth of the cell process to a desired location on the surface; though it does not include the additional

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features of an aperture, a reservoir connected to the aperture, or a flow regulator in operable relationship with the reservoir to move the fluid to the aperture, these modifications would all be obvious in order to more efficiently direct the growth of the cell process by supplying nutrients or chemoattractant factors. Claim 3 of the copending application does require the device to further comprise an aperture. Claim 6 of the copending application does require the device to further comprise a reservoir connected to the aperture. Claim 40 of the copending application requires the device to comprise a photosensitive device (which is called a photodiode in the current application). Claim 43 of the copending application does require the device to further comprise a fluid delivery channel configured to direct fluid to a desired location. Claim 36 of the copending application requires the device to be implantable in the subretinal space. Though no claim of the copending application comprises all of the above features, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine all the features of copending claims 3, 6, 40 and 43 to create a neuronal device that comprises a housing with an exterior surface biocompatible with at least a portion of a neuronal cell, an aperture in the exterior surface, a reservoir in the interior connected to the aperture, an electrically controlled flow regulator comprised of a fluid delivery channel designed to move fluid from the reservoir to the aperture, and wherein the exterior surface is micropatterned to direct the growth of a neuronal process to a desired location, such as the aperture. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine all the features of the devices of the copending application in order to create a device capable of directing neuronal cell process growth by means of micropatterning and neuromodulatory agents, efficiently supplied by fluid pumps from a reservoir, through an aperture, to the micropatterns, in order to modulate the regrowth and regeneration of nerves in the subretinal regions of the eye.

Both claim sets have the same general features, including a micropatterned substrate for directing neuronal cell processes to apertures connected to reservoirs, and wherein the fluid in the

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reservoirs is moved by a microfluidic device or flow regulator. Both devices are intended to function as ocular implants for nerve regeneration, implantable in the subretinal region of the eye.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

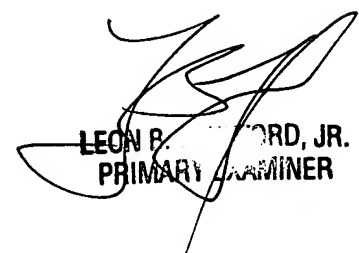
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M Ford whose telephone number is 571-272-2936. The examiner can normally be reached on M-F 7:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651


LEON B. FORD, JR.
PRIMARY EXAMINER